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Joseph C. Mase et al.

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Examiner  
Kumiko C. Koyama

TITLE  
CODING SYMBOLOGY AND A METHOD FOR PRINTING SAME

**APPEAL BRIEF**

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(1) REAL PARTY IN INTEREST

The real party in interest in this appeal is Baxter International Inc., assignee of the invention claimed in the above referenced application, which assignment was recorded in the United States Patent and Trademark Office at Reel No. 012910 and Frame No. 0407 on May 20, 2002, in the current application.

(2) RELATED APPEALS AND INTERFERENCES

None.

(3) STATUS OF CLAIMS

Applicant is appealing the rejection of claims 1-7, 10-25 and 33-71. Claims 8, 9 and 26-32 are cancelled.

(4) STATUS OF AMENDMENTS

No amendments were filed after final rejection.

(5) SUMMARY OF THE CLAIMED SUBJECT MATTER

The present invention is directed to novel apparatus, systems and methods that comprise or provide a negative image bar code which represents at least variable information, and preferably both fixed and variable information, through a single printing process on clear plastic film. As compared to prior art systems and methods, the bar code of the present invention may be represented on the clear plastic film without requiring any further printing or labeling processes to create a bar code

that comprises variable or both fixed and variable information. The clear plastic film itself defines light absorbing segments between light reflective segments of the bar code so that such information is detectable using a reader (paragraph 22, lines 1-7, paragraph 23, lines 1-2 of the published application).

Independent Claim 1

As recited in independent Claim 1, one aspect of the present invention provides a medical container having a negative image bar code 20 representing both fixed and variable information on such container (e.g., substrate 30) (see Fig. 1; paragraph 34, lines 1-4). In Claim 1, the container 30 comprises a transparent plastic film (see Fig. 1, paragraph 35). A plurality of light-reflecting segments 22 are disposed on the container film, with spaces 24 separating adjacent light-reflecting segments 22 (see Fig. 1; paragraph 34, lines 4-6). The spaces are defined by the transparent plastic container film, and the film defining the spaces also itself defines light-absorbing segments 26 (see Fig. 1; paragraph 34, lines 6-7). Together, the light-reflecting segments 22 and the light-absorbing segments 26 define a negative image bar code 20 representing both fixed and variable information which are detectable by a reader (see Fig. 1, paragraph 34, lines 8-

11). The variable information includes at least one of a lot number batch number, expiration date serial number, production time, price and concentration.

By accommodating the variable information as part of the bar code, the bar code comprises information which changes more often (i.e., variable information), as opposed to fixed information which remains unchanged for a longer or set period. In one aspect of the present invention, such changes are preferably accommodated using a thermal transfer printing system (as compared to prior art hot-stamping systems) (paragraph 18, lines 8-13). The differences between the fixed and variable information is described in the current application as follows:

[0038] According to the invention, fixed information is defined to be information that remains unchanged for a first period of time while variable information is defined to be information that changes during the first period. Examples of fixed information include, but are not limited to, a product's: name, code number, manufacturer, National Drug Code Number, label copy data required by the Federal Food & Drug Administration (FDA), or data required by the Health Industry Bar Code Council, now known as the Health Industry Business Communications Council (HIBCC), and the like. Examples of variable information include, but are not limited to, a product's: lot number, batch number, expiration date, serial number, production time, price, inventory control data, and concentration. (paragraph 38)

Independent Claim 14

Independent claim 14 is similar to claim 1, but is directed to a "container" generally, instead of a "medical container".

Independent Claim 15

In another aspect of the present invention, as set forth in independent Claim 15, a medical container has first and second negative image bar codes, the first negative image representing fixed information and the second negative image representing variable information. More specifically, the medical container comprises transparent plastic film. A first negative image bar code 40 representing fixed information and a second negative image bar code 50 representing variable information are located on the medical container and are each detectable using a reader (see Fig. 2; paragraph 39, lines 5-7). As recited in Claim 15, the first bar code 40 comprises a first plurality of light-reflecting segments 42 disposed on the container film. The clear container film defines spaces 44 that separate the first light-reflecting elements. The film defining the spaces also itself defines a first set of light-absorbing segments 46. Together, the first plurality of light-reflecting segments 40 and first

set of light-absorbing segments 46 define the first negative image bar code (Fig. 2; paragraph 39, lines 7-12).

As further set forth in Claim 15, the second bar code 50 comprises a second plurality of light-reflecting segments 52 disposed on the film and the container film defines spaces 54 between the light-reflective segments, and the clear container film defining the spaces also itself defines a second set of light-absorbing segments 56 (Paragraph 40, lines 1-6). Together, the second plurality of light-reflecting segments and the second set of light-absorbing segments define a second negative image bar code representing information that comprises at least one selected from the group consisting of lot number, bath number, expiration date, serial number, production time, price and concentration.

Independent Claim 16

In a further aspect of the claimed invention, as set forth in claim 16, a medical container comprises a transparent plastic film. A plurality of light-reflecting segments 54 are disposed on the film. The film defines spaces that separate the reflecting segments and the film defining the spaces also itself defines light absorbing segments (see Fig. 2). Such light-reflecting segments 54 and light-absorbing segments 56 together define a negative

image bar code 50 that represents variable information, such as shown in Fig. 2. As compared to Claim 15, for example, Claim 16 recites a bar code for variable information only, and does not require a bar code 40 that also represents fixed information.

Independent Claim 17

Claim 17 is similar to claim 16, but is directed generally to a "container" instead of a "medical container".

Independent Claim 18

Claim 18 is directed to another significant aspect of the present invention in which the bar code, as described above, is readable through a material positioned over a portion of the bar code -- for example, through an overpouch containing a medical container having such a bar code. More particularly, Claim 18 is directed to a container system comprising a medical container (see 80 in Fig. 3) including transparent plastic film. A plurality of light-reflecting segments 72 are disposed on the container film and the container film defines spaces that separate the plurality of light-reflecting segments 74. The film defining the spaces also itself defines light-absorbing segments. Together, the light-reflecting and light-absorbing segments define a negative image bar code 70

representing fixed and variable information. The bar code is readable through a material 92, for example, an overpouch, positioned over a portion of the bar code. Specifically the portion of the bar code has an A or B scan grade when decoded through the material in accordance with ANSI X3.182 (see Fig. 3, paragraph 44, lines 9-16; paragraph 45, lines 1-6).

Independent Claim 19

Claim 19 is similar to claim 18, but requires a first negative image bar code representing fixed information and a second negative image bar code representing variable information. A material (e.g. an overpouch) is positioned over a portion of each bar code - - and each portion has an A or B scan grade when decoded through the material.

Independent Claim 20

Claim 20 is directed to a container system comprising a medical container similar to claim 19, except that the negative image bar code defined in claim 20 represents variable information and there is no requirement of a bar code representing fixed information.

Independent Claim 21

Claim 21 is comparable to claim 18, but specifies that the variable information includes at least one of the lot

number, batch number, expiration date, serial number, production time, price and concentration.

Independent Claim 22

Claim 22 is comparable to claim 16, requiring only a negative image bar code representing variable information, but is directed to a "container" generally, instead of a "medical container".

Independent Claim 23

In a yet further aspect of the present invention, a method, as set forth in independent Claim 23, comprises the step of providing a flexible transparent plastic web, such as a web of material (paragraph 67, lines 1-8). The method of Claim 23 also comprises the step of providing a printer capable of transferring a plurality of light-reflecting segments onto the web in response to a signal representative of the plurality of light-reflecting segments (paragraph 67, lines 8-18). As further set forth in Claim 23, the method comprises the steps of transferring the signal to the printer (paragraph 68, lines 1-3) and transferring the plurality of light-reflecting segments onto the web (paragraph 69, lines 1-3).

Similar to other aspects of the present invention, the method of Claim 23 provides that the transparent plastic web defines spaces that separate the plurality of light-

reflecting segments such that the web that defines the spaces also itself defines a plurality light-absorbing segments (see Figs. 1-3). Also, in accordance with previously described aspects, the method provides that the light-reflecting segments and the light-absorbing segments define a negative image bar code that can be detected by a reader and which represents fixed information and variable information (see Figs. 1-3). The variable information comprises at least one of the lot number, batch number, expiration date, serial number, production time, price and concentration.

Independent Claim 25

Claim 25 is directed to a container system similar to claim 18 except that it does not require the bar code to represent fixed information and is not limited to a medical container. Claim 25 also specifies that the variable information comprise at least one of the lot number, batch number, expiration date, serial number, production time, price and concentration.

Independent Claim 63

In a yet further aspect of the present invention, as set forth in independent Claim 63, a medical container is comprised of a transparent plastic film and has a negative image bar code. The film itself defines at least two

spaces in the bar code which absorb the light such that the negative image bar code is detectable with a bar code reader. In such aspect, the negative image bar code comprises variable information that includes at least one of the different types of variable information previously described (see Figs. 1-3).

(6) GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

(A) The rejection of independent claims 1, 14-17, 22 and 63 under 35 U.S.C. 103(a) as being unpatentable over Takada (US 5,237,164) in view of Small et al. (US 6,355,024).

(B) The rejection of independent claims 18-21 and 25 under 35 U.S.C. 103(a) as being unpatentable over Takada in view of Small et al. and McGinty et al. (US 6,010,970).

(C) The rejection of independent Claims 23 under 35 U.S.C. 103(a) as being unpatentable over Takada in view of Small et al. and Berquist (US 4,884,904).

(7) ARGUMENT

For the purposes of the argument against the Examiner's rejection of the pending claims, the claims are being grouped consistently with the Examiner's rejections thereof. Specifically, Claims 1, 14-17, 22 and 63 comprises a first group, Claims 18-21 and 25 comprise a

second group, and Claim 23 comprises a third group. The patentability of the various dependent claims is not being argued separately from the independent claims from which they depend. Thus, for purposes of clarity, no reference to the dependent claims is made in appellant's argument.

A. Claims 1, 14-17, 22 and 63 are Patentable over the combination of Takada and Small et al.

Claims 1, 14-17, 22 and 63 stand rejected for obviousness over the combination of Takada and Small et al.

Turning to Claim 1, which is exemplary of Claims 1, 14-17, 22 and 63, Claim 1 is directed to a medical container having a negative image bar code. The container comprises transparent plastic film. A plurality of light-reflecting segments are disposed on that film. Unlike any teaching of Takada or Small et al., the container film itself (i.e., the transparent plastic film) defines light-absorbing segments between the light-reflecting segments.

As further set forth in Claim 1, the light-reflecting segments and the light-absorbing segments define a negative image bar code representing both fixed and variable information. The variable information comprises at least one selected from the group consisting of lot number, batch number, expiration date, serial number, production time, price and concentration. As noted in the application,

prior hot stamping systems for printing a bar code are particularly unsuited for printing variable information, which changes in a fixed time period, such as by the minute, hour or day (paragraph 16, lines 6-10). The negative image bar code, which contains both fixed and variable information, is detectable using a reader.

It is respectfully submitted that Takada in combination with Small et al. neither discloses or suggests the claimed medical container. First, the combination of Takada and Small et al. fails to teach a bar code wherein the clear container film itself forms part of the code.

Each of claims 1, 14-17, 22 and 63 calls for transparent plastic film upon which the bar code is disposed. The claims further require that the film defines spaces that separate the light-reflecting element and that the film defining the spaces (i.e., the transparent plastic film) also itself defines light-absorbing segments. As noted above, the light-reflecting segments and light-absorbing segments define a negative image bar code representing both fixed information and variable information. No coating, label, sticker or background printing is required to provide the light-absorbing

segments. The claimed combination is not disclosed or suggested by Takada in combination with Small et al.

Specifically, Takada describes a card having a retroreflective bar code where the code is formed with black bars (or white bars) of the bar code printed on a prior art sheet of paper where the retroreflective material is stuck to a base plate (column 1, lines 52-56, 65-68), or, alternatively, where the transparent stripes and opaque stripes are formed so as to form a bar code stuck to a sheet formed of a sheet of retroreflective material (column 2, lines 4-8).

The Examiner asserts that the substrate supporting the retroreflective bar code is "unchanged", with the card substrate per se acting as the light-absorbing segments of the bar code. However, this is a misunderstanding or misreading of Takada. Takada clearly states that the "dark portion" (or the light-absorbing segments) of the bar code is formed by printing a black, light-absorbing color onto the card substrate. Specifically, and with reference to Figure 4 of Takada, a dark portion 28b of the card substrate 28a can be formed by a printing process of black color to have a light absorption property. Takada states:

Referring to FIG. 4, there is shown a card substrate 28. A retroreflective material 29 is stuck to a bright portion 28a on the card substrate 28. The

bright portion 28a reflects light incident thereon. A dark portion 28b of the card substrate 28 is left unchanged because it is not needed to reflect incident light. The dark portion 28b can be formed by a printing process of black color having a light absorption property or the like. (Column 5, lines 39-46).

The reference in Takada to the substrate being "unchanged" clearly means only that it is unchanged in that there is no addition of retroreflective material. The reference in Takada does not mean that the substrate is "unchanged" with respect to its light-absorbing characteristics, as the Examiner asserted in the rejections. Contrary to the Examiner's assertion, the light-absorbing characteristics of the substrate are provided, e.g., by printing a black color thereon. Takada thus teaches that to form the bar code, the dark (light-absorbing) portion of the bar code is first printed on the card. This portion is then combined with the retroreflective material to form the bar code. Thus, the unchanged card (prior to the black printing) itself in Takada does not form part of the bar code (the light absorbing portions being printed black and the light reflections portion being added retroreflective material). Thus, there is no teaching or suggestion in Takada of using

an unprepared or unmodified substrate material to form the light-absorbing portion of a negative image bar code.

Even if there were such a teaching, Takada provides no suggestion of the use of a transparent plastic film for the light absorbing segments of a negative image bar code. Indeed, the bar code-containing card of Takada must be attached to the article to be scanned, requiring additional steps or assembly. In contrast, as exemplified in Claim 1, the medical container, film or web of the present invention comprises transparent plastic film which itself defines the light-absorbing segments of the bar code. No paper, card, sticker or printing is necessary to define the light absorbing segments in the amended claims. Each of the other independent claims recites a similar feature. In other words, unlike in Takada, the article claimed (for example, the container, medical container, web, film, etc., or the method for making the article) has a negative image bar code in which the transparent plastic film itself defines the light absorbing segments of the bar code. The bar code contains variable information or fixed information and variable information and is detectable by a reader.

The Small et al. patent does not supply the features missing from Takada or provide the motivation to make the claimed combination. Small et al. merely states that the

bulk container or delivery container may have an identifier  
76 such as a magnetic strip that is readable by a  
computerized information system. However, Small et al.  
specifically states:

"the identifier 76 may be a sticker containing, for example, a bar code, a radio frequency source or a micro chip, it may contain a variety of information such as product name, source, concentration, lot number, expiration date, whether the package has been previously used, etc" (emphasis added). (Column 14, lines 1-6).

The use of a sticker, which is the contemplated arrangement in Small et al., is precisely what the present invention, at least in part, is trying to avoid.

Accordingly, modification of Takada in view of Small et al. does not lead to the claimed invention, but leads away from it. The logical result of combining Takada and Small et al., even if there was motivation to make such a combination, would not be the claimed negative image bar code in which transparent plastic film of the container itself defines the light-absorbing segments. Instead, if Takada and Small et al. were combined, the result would be a container having a sticker, in which part of the sticker has a printed background for light absorbency and employs retroreflective material to increase readability of a bar code at a distance.

Therefore, it is respectfully submitted that even if Takada and Small et al. were combined, the logical combination would not yield the claimed invention.

Even of Takada and Smith et al. resulted in the combination of claim 1 (which they do not), it is further respectfully submitted that the requisite motivation, separate from the present application, to combine Takada and Small et al. is absent. There is no teaching or suggestion of taking advantage of light absorbing properties of clear plastic film to form the light absorbing segments of a negative image bar code. Further, Takada focuses on the importance of reading bar codes from a significant distance, presumably for employee identification cards, in a manufacturing facility or the like. None of the references suggests or teaches that it is important to read bar codes on medical containers from a significant distance. To the contrary bar codes on containers such as medical containers are normally scanned in close proximity at the time of prescription or administration by pharmacist, physician or nurse.

In this regard, Takada is nonanalogous prior art, and is directed to solving a problem that is not really existent in connection with bar codes on medical containers. Takada would appear to be of principal

application to large industrial or commercial settings where, for example, company identification cards or the like need to be read at a great distance, such 10's of meters, and from a variety of different angles (see, e.g., column 2, lines 43-47, 65-68, column 9, lines 15-26). Applicant is not aware of any suggestion in Takada or Small et al. that such problems or objectives are associated with reading bar codes on medical fluid containers. As noted above, typically those bar codes are read in close proximity to the container such as at the medical station or dispensary where the contents of the container are being prescribed or administered to a patient. It is therefore respectfully submitted that there is no motivation for combining Takada and Small et al., and only impermissible hindsight based on the present application would lead one of ordinary skill in the art to the claimed invention.

In any event, Takada in combination with Small et al. neither describes or suggests the invention claimed in claims 1, 14-17, 22 and 63, in which a negative image bar code representing variable or fixed and variable information is provided on transparent plastic container film in which the container film itself defines the light absorbing segments between the light reflecting segments of the bar code.

B. Claims 18-21 and 25 are Patentable over the Combination of Takada, Small et al. and McGinty et al.

Claims 18-21 and 25 stand rejected for obviousness over the combination of Takada and Small et al. and further in view of McGinty et al. Appellant's argument with respect to the combination of Takada and Small et al. is set forth in section A above and will not be repeated here in full. To the extent that Takada and Small et al. do not disclose or suggest the claimed combination and lack motivation to make the combination, the obviousness conclusion reached by the Examiner is even more tenuous when the Examiner must rely upon yet a third patent to support an obviousness rejection.

The Examiner concedes that the combination of Takada and Small et al. does not disclose an A or B scan grade when decoded through the material and in accordance with ANSI X3.182.

The Examiner cites McGinty et al. for disclosing "a bar code readability grade, according to ANSI standard X3.182-1990, of at least 3.0 (Grade B), using Code 39 symbology with a narrow band width of 0.0096 inch (0.0244 cm) (column 3, lines 47-52)."

Turning to Claim 18, which is exemplary of Claims 18-21 and 25, Claim 18 is directed to a container system

comprising a medical container made of a transparent plastic film and having a negative image bar code disposed thereon. In the bar code, the plastic film defines the light-absorbing spaces that separate the light-reflecting segments of the bar code to represent both fixed information and variable information. In addition, the container system includes a material which is positioned over a portion of the bar code. The portion of the bar code over which the material is positioned may be decoded or detected through the material in accordance with the recited ANSI standards. Specifically, each of Claims 18-21 and 25 requires, substantially, "a material positioned over a portion of the [or each] bar code, wherein the portion has an A or B scan grade when decoded through the material in accordance with ANSIX3.182." This has particular value in medical fluid containers which are often packaged in a protective overpouch that is not removed until the point of administration.

McGinty et al. teaches a flash spun plexifilamentary sheet material that incorporates a titanium dioxide pigment such that, when a bar code is printed thereon, has a bar code readability grade of at least 3.0 (Grade B). There is no indication in McGinty et al. that the readability grade is taken through a material, such as an overpouch,

positioned over the bar code. McGinty et al. either alone, or in combination with Takada and Small et al., teaches nothing with respect to positioning a material over a portion of the bar code through which the bar code is decoded at a specified scan grade.

In addition, the bar code described in McGinty et al. is a positive image bar code -- not a negative image bar code as required by each of Claims 18-21 and 25. Indeed, a negative image bar code (in which the light-reflecting segments of the bar code are printed or otherwise disposed on the film) would not work with the sheet material described in McGinty et al., as the titanium dioxide pigment makes the sheet light reflective (see column 7, lines 52-56). Thus, the scan grade specified in McGinty et al. is completely irrelevant with respect to the claimed invention.

Thus, Takada in combination with Small et al. and in view of McGinty et al. neither describes or suggests the invention of claims 18-21 and 25, in which a negative image bar code representing variable or fixed and variable information is provided on transparent plastic film in which the film itself defines the light absorbing segments between the light reflecting segments of the bar code and further having a material positioned over at least a

portion of the bar code, with the covered portion of the bar code still having an A or B scan grade through the overlying material.

C. Claim 23 is Patentable over the Combination of Takada, Small et al. and Berquist

Claim 23 stands rejected for obviousness over the combination of Takada and Small et al. and further in view of Berquist. Appellant's argument with respect to the combination of Takada and Small et al. is set forth in section A above, and will not be repeated here.

The Examiner asserts that Berquist teaches a bar code printer for printing data on a web of material, the printer being a thermal print head type printer, and inputting a signal to the printer. The Examiner concludes that it would have been obvious to an artisan of ordinary skill in the art at the time the invention was made to integrate the teachings of Berquist to the teachings of Takada as modified by Small et al. in order to print the bar code so that the bar code can be generated to represent information and identify the item to which the bar code is applied, therefore providing a unique identification to quickly identify and obtain information about the item.

Claim 23 is directed to a method that comprises the steps of providing a flexible transparent plastic web,

providing a printer capable of transferring a plurality of light-reflecting segments onto the web in response to a signal representative of the plurality of light-reflecting segments, transferring the signal to the printer and transferring the plurality of light-reflecting segments onto the web. Similar to other aspects of the present invention, the method of Claim 23 provides that the transparent plastic web defines spaces that separate the plurality of light-reflecting segments such that the web itself defines a plurality light-absorbing segments. Also, in accordance with previously described aspects, the method provides that the light-reflecting segments and the light-absorbing segments define a negative image bar code that can be detected by a reader and which represents fixed information and variable information.

Appellant submits that there is no motivation to combine Takada, Small et al. and Berquist other than the disclosure of the pending application (which may not be relied upon) and, further, there is no reasonable expectation that the combination would successfully achieve the claimed invention.

Berquist teaches a label printing device that includes a thermal printhead for printing bar codes on a web of printing medium. Takada teaches a retroreflective bar code

formed by selectively heating, distorting and crushing "glass beads, plastic beads, or the like." Specifically, in Takada, "the retroreflective material is formed by depositing a number of very small glass beads 29a on a mount 29b made of paper or the like." (Column 5, lines 46-49). The mount 29a is then stuck onto the card substrate. It is unlikely that a bar code formed by depositing glass beads onto a substrate, as taught by Takada, could be applied by the thermal printhead used in the bar code printer of Berquist.

Further, retroreflective the bar code taught by Takada is typically applied to company ID cards (see, e.g., column 1, lines 15-34; column 2, lines 18-44; and column 5, lines 21-24). As such, the "life span" of the information recorded in the bar code is long. Consequently, such a bar code would not contain variable information, as such a bar code is simply not suited for information that is apt to change.

In any case, the combination of Takada, Small et al., and Berquist at most teaches making positive image bar code labels or stickers having fixed information. Accordingly, Appellant submits that Berquist cannot be combined with Takada and Small et al. to achieve the invention as set forth in Claim 23, as there is no teaching that the web to

which the negative image bar code is applied defines the light-absorbing segments of a negative image bar code that includes variable information.

D. Conclusion

For the foregoing reasons, it is respectfully requested that the Examiner's rejection of the pending claims be reversed and the claims allowed.

Date: MAY 13, 2005

Respectfully submitted,

  
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(8) CLAIM APPENDIX

1. (Previously Presented) A medical container having a negative image bar code comprising:

a medical container comprising transparent plastic film

a plurality of light-reflecting segments disposed on the container film,

wherein the container film defines spaces that separate the light-reflecting segments,

wherein the film defining the spaces also itself defines light-absorbing segments,

wherein the light-reflecting segments and the light-absorbing segments define a negative image bar code representing fixed information and variable information,

wherein the negative image bar code is detectable using a reader, and

wherein the variable information comprises at least one selected from the group consisting of: lot number, batch number, expiration date, serial number, production time, price, and concentration.

2. (Previously Presented) The medical container of claim 1 wherein the light-reflecting segments are indicia that can be detected by a reader.

3. (Previously Presented) The medical container of claim 2 wherein the indicia is visible to the naked human eye.

4. (Previously Presented) The medical container of claim 3 wherein the indicia has a color selected from the group consisting of white, red, yellow, orange, gold, and silver.

5. (Previously Presented) The medical container of claim 2 wherein the indicia is not visible to the naked human eye.

6. (Previously Presented) The medical container of claim 1 wherein the fixed information remains unchanged for a first period of time while the variable information changes during the first period.

7. (Previously Presented) The medical container of claim 1 wherein the fixed information is selected from the group consisting of product name, product manufacturer, Universal Product Code, Universal Product Number, National Drug Code, National Health Related Industry Code, and label copy data.

8. (Canceled)

9. (Canceled)

10. (Previously Presented) The medical container of claim 1 wherein the medical container film comprises a thermoplastic polymer or a thermoset polymer.

11. (Previously Presented) The medical container of claim 10 wherein the thermoplastic polymer or the thermoset polymer is selected from the group consisting of polyvinylchloride, polyvinylchloride, polyolefins, polyamides, polycarbonates, polyesters, thermoplastic elastomers, elastomers, polyimides, polyurethanes, ethylene vinyl alcohol copolymers, ethylene vinyl acetate copolymers, ethylene copolymers, propylene copolymers, acrylic acid copolymers, ethylene substituted acrylic acid copolymers,  $\alpha$ -olefin substituted acrylic acid copolymers, hydrocarbon block polymers, ethylene propylene diene polymers, nylon, mono-layer film structures and multi-layer film structures.

12. (Previously Presented) The medical container of claim 11 wherein the polyolefin is produced from an  $\alpha$ -olefin having from about 2 to about 20 carbons.

13. (Previously Presented) The medical container of claim 12 wherein the  $\alpha$ -olefin is ethylene or propylene.

14. (Previously Presented) A container having a negative image bar code, the container comprising:

a flexible transparent plastic film;  
    a plurality of light-reflecting segments disposed on  
the film,

    wherein the film defines spaces that separate the  
light-reflecting segments,

    wherein the film defining the spaces also itself  
defines light-absorbing segments,

    wherein the light-reflecting segments and the light-  
absorbing segments define a negative image bar code  
representing fixed information and variable information,

    wherein the variable information comprises at least  
one selected from the group consisting of: lot number,  
batch number, expiration date, serial number, production  
time, price, and concentration, and

    wherein the negative image bar code is detectable  
using a reader.

15. (Previously Presented) A medical container having  
a negative image bar code comprising:

    a medical container comprising transparent plastic  
film;

    a first plurality of light-reflecting segments  
disposed on the medical container film, wherein the medical  
container film defines first spaces that separate the first  
plurality of light-reflecting segments, wherein the film

defining the first spaces also itself defines a first set of light-absorbing segments, and wherein the first plurality and the first set define a first negative image bar code representing fixed information;

a second plurality of light-reflecting segments disposed on the medical container film, wherein the medical container film defines second spaces that separate the second plurality of light-reflecting segments, wherein the film defining the second spaces also itself defines a second set of light-absorbing segments, wherein the second plurality and the second set define a second negative image bar code representing variable information, wherein the variable information comprises at least one selected from the group consisting of: lot number, batch number, expiration date, serial number, production time, price, and concentration; and

wherein the first bar code and the second bar code are each detectable using a reader.

16. (Previously Presented) A medical container having a negative image bar code comprising:

a medical container comprising transparent plastic film;

a plurality of light-reflecting segments disposed on the medical container film, wherein the medical container

film defines spaces that separate the plurality of light-reflecting segments, and wherein the film defining the spaces also itself defines light-absorbing segments;

wherein the light-reflecting segments and the light-absorbing segments define a negative image bar code representing variable information;

wherein the negative image bar code is detectable using a reader; and

wherein the variable information comprises at least one selected from the group consisting of: lot number, batch number, expiration date, serial number, production time, price and concentration.

17. (Previously Presented) A container comprising:  
a flexible transparent plastic film;  
a plurality of light-reflecting segments disposed on the flexible film, wherein the flexible film defines spaces that separate the plurality of light-reflecting segments, wherein the film defining the spaces also itself defines a set of light-absorbing segments, wherein the plurality and the set define a negative image bar code representing variable information, wherein the bar code is detectable using a reader, and wherein the variable information comprises at least one selected from the group consisting

of: lot number, batch number, expiration date, serial number, production time, price and concentration.

18. (Previously Presented) A container system comprising:

a medical container comprising transparent plastic film;

a plurality of light-reflecting segments disposed on the medical container film, wherein the medical container film defines spaces that separate the plurality of light-reflecting segments, wherein the film defining the spaces also itself defines light-absorbing segments, wherein the light-reflecting segments and the light-absorbing segments define a negative image bar code representing fixed information and variable information, and

a material positioned over a portion of the bar code, wherein the portion has an A or B scan grade when decoded through the material and in accordance with ANSI X3.182.

19. (Previously Presented) A container system comprising:

a medical container comprising transparent plastic film;

a first plurality of light-reflecting segments disposed on the medical container film, wherein the medical container film defines first spaces that separate the first

plurality of light-reflecting segments, wherein the film defining the first spaces also itself defines a first set of light-absorbing segments, and wherein the first plurality and the first set define a first negative image bar code representing fixed information;

a second plurality of light-reflecting segments disposed on the medical container film, wherein the medical container film defines second spaces that separate the second plurality of light-reflecting segments, wherein the film defining the second spaces also itself defines a second set of light-absorbing segments, and wherein the second plurality and the second set define a second negative image bar code representing variable information;

and

a material positioned over a portion each bar code, wherein each portion has an A or B scan grade when decoded through the material and in accordance with ANSI X3.182.

20. (Previously Presented) A container system comprising:

a medical container comprising transparent plastic film;

a plurality of light-reflecting segments disposed on the medical container film, wherein the medical container film defines spaces that separate the plurality of light-

reflecting segments, wherein the film defining the spaces also itself defines a set of light-absorbing segments, wherein the plurality and the set define a negative bar code representing variable information;

a material positioned over a portion of the bar code, and

wherein the portion of the bar code has an A or B scan grade when decoded through the material and in accordance with ANSI X3.182.

21. (Previously Presented) A container system comprising:

a flexible container comprising a transparent plastic film;

a plurality of light-absorbing segments disposed on the flexible container film, wherein the flexible container film defines spaces that separate the plurality of light-reflecting segments, wherein the film defining the spaces also itself defines light-absorbing segments, wherein the light-reflecting segments and the light-absorbing segments define a negative image bar code representing fixed information and variable information, wherein the variable information comprises at least one selected from the group consisting of: lot number, batch number, expiration date,

serial number, production time, price, and concentration, and wherein the bar code is detectable using a reader;

a material positioned over a portion of the bar code, wherein the portion of the bar code has an A or B scan grade when decoded through the material and in accordance with ANSI X3.182.

22. (Previously Presented) A container comprising:  
a transparent plastic film that defines the container  
a plurality of light-reflecting segments disposed on the film, wherein the film defines spaces that separate the light-reflecting segments, wherein film defining the spaces also itself defines a set of light absorbing segments, wherein the plurality and the set define a negative image bar code representing variable information, wherein the bar code can be detected by a reader, and wherein the variable information comprises at least one selected from the group consisting of: lot number, batch number, expiration date, serial number, production time, price, and concentration.

23. (Previously Presented) A method of transferring a negative image bar code onto a flexible web comprising the steps of:

providing a flexible transparent plastic web;  
providing a printer capable of transferring a plurality of light-reflecting segments onto the web in

response to a signal representative of the plurality of light-reflecting segments,

transferring the signal to the printer; and  
transferring the plurality of light-reflecting segments onto the web, wherein the transparent plastic web defines spaces that separate the plurality of light-reflecting segments, wherein the web that defines the spaces also itself defines a plurality light-absorbing segments, wherein the light-reflecting segments and the light-absorbing segments define a negative image bar code that can be detected by a reader, wherein the negative image bar code represents fixed information and variable information, and wherein the variable information comprises at least one selected from the group consisting of: lot number, batch number, expiration date, serial number, production time, price, and concentration.

24. (Previously Presented) The method of claim 23 wherein the printer is a thermal transfer printer, a hot-stamp printer, a laser printer, an ink-jet printer, or a flexographic printer.

25. (Previously Presented) A container system comprising:

a flexible container comprising a transparent plastic film;

a plurality of light-reflecting segments disposed on the flexible container film, wherein the flexible container film defines spaces that separate the plurality of light-reflecting segments, wherein the film that defines the spaces also itself defines light-absorbing segments, wherein the light-reflecting segments and the light-absorbing segment define a negative image bar code representing variable information, wherein the variable information comprises at least one selected from the group consisting of: lot number, batch number, expiration date, serial number, production time, price, and concentration; and

a material positioned over a portion of the negative image bar code, wherein the portion of the bar code has an A or B scan grade when decoded through the material and in accordance with ANSI X3.182.

26-32. (canceled)

33. (Previously Presented) The container of claim 14 wherein the container is a medical container.

34. (Previously Presented) The container of claim 33 wherein the light-reflecting segments are indicia having a color selected from the group consisting of white, red, yellow, orange, gold, and silver.

35. (Previously Presented) The medical container of claim 34 wherein the negative image bar code comprises a symbology selected from the group consisting of: Code 16K, Code 39, Code 49, Codabar, Code 128, UPC-E, UPC-A, EAN-8, EAN-13, Reduced Space Symbology, composite symbol, PDF-417, and Interleaved 2-of-5.

36. (Previously Presented) The medical container of claim 34 wherein the negative image bar code is a two-dimensional symbology.

37. (Previously Presented) The medical container of claim 15 wherein the medical container is flexible.

38. (Previously Presented) The medical container of claim 15 wherein the first or second negative image bar code comprises a symbology selected from the group consisting of: Code 16K, Code 39, Code 49, Codabar, Code 128, UPC-E, UPC-A, EAN-8, EAN-13, Reduced Space Symbology, composite symbol, PDF-417, and Interleaved 2-of-5.

39. (Previously Presented) The medical container of claim 16 wherein the medical container is flexible.

40. (Previously Presented) The medical container of claim 16 wherein the light-reflecting segments are indicia having a color selected from the group consisting of white, red, yellow, orange, gold, and silver.

41. (Previously Presented) The medical container of claim 40 wherein the negative image bar code comprises a symbology selected from the group consisting of: Code 16K, Code 39, Code 49, Codabar, Code 128, UPC-E, UPC-A, EAN-8, EAN-13, Reduced Space Symbology, composite symbol, PDF-417, and Interleaved 2-of-5.

42. (Previously Presented) The medical container of claim 40 wherein the negative image bar code is a two-dimensional symbology.

43. (Previously Presented) The container of claim 17 wherein the container is a medical container.

44. (Previously Presented) The container of claim 43 wherein the negative image bar code has a length less than 72 millimeters.

45. (Previously Presented) The container of claim 43 wherein the negative image bar code has a length less than or equal to 52 millimeters.

46. (Previously Presented) The container of claim 43 wherein the negative image bar code has a length less than or equal to 22 millimeters.

47. (Previously Presented) The container system of claim 18 wherein the negative image bar code has a length less than 72 millimeters.

48. (Previously Presented) The container system of claim 18 wherein the negative image bar code has a length less than or equal to 52 millimeters.

49. (Previously Presented) The container system of claim 19 wherein the negative image bar code has a length less than 72 millimeters.

50. (Previously Presented) The container system of claim 19 wherein the negative image bar code has a length less than or equal to 52 millimeters.

51. (Previously Presented) The container system of claim 19 wherein the second plurality of light-reflecting segments are indicia having a color selected from the group consisting of white, red, yellow, orange, gold, and silver.

52. (Previously Presented) The container system of claim 20 wherein the medical container is flexible.

53. (Previously Presented) The container system of claim 52 wherein each bar code has a length less than 72 millimeters.

54. (Previously Presented) The container system of claim 52 wherein the material is an overpouch comprising polyethylene, and wherein the overpouch has a thickness of at least 2 mils.

55. (Previously Presented) The container system of claim 54 wherein the thickness of the overpouch is at least 4 mils.

56. (Previously Presented) The container system of claim 54 wherein the thickness of the overpouch is at least 8 mils.

57. (Previously Presented) The container system of claim 52 wherein each bar code has a length less than 52 millimeters.

58. (Previously Presented) The container system of 21 wherein the bar code has a length less than 72 millimeters.

59. (Previously Presented) The container of claim 22 further comprising a second plurality of light-reflecting segments disposed on the film, wherein the film defines spaces that separate the second plurality of light-reflecting segments, wherein the film defining the spaces also itself defines a second set of light-absorbing segments, wherein the second plurality and the second set define a second negative image bar code, wherein the second negative image bar code can be detected by a reader, and wherein the second negative image bar code represents fixed information.

60. (Previously Presented) The container of claim 59

wherein each negative image bar code is characterized in having an A or B scan grade when decoded in accordance with ANSIX3.182 through an overpouch comprising polyethylene, wherein the overpouch has a thickness of at least 2 mils.

61. (Previously Presented) The container of claim 60 wherein each negative image bar code has a length less than 72 millimeters.

62. (Previously Presented) The container of claim 60 wherein each negative image bar code has a length less than or equal to 52 millimeters.

63. (Previously Presented) A medical container comprised of transparent plastic film and having a bar code comprising:

a negative bar code disposed on the medical container film,

wherein the film of the medical container itself defines at least two spaces in the bar code, the spaces absorbing light,

wherein the negative image bar code is detectable with a bar code reader,

wherein the negative image bar code comprises variable information, and

wherein the variable information comprises at least one selected from the group consisting of: lot number,

batch number, expiration date, serial number, production time, price, and concentration.

64. (Previously Presented) The medical container of claim 63 wherein the medical container is flexible.

65. (Previously Presented) The medical container of claim 64 wherein the bar code further comprises fixed information.

66. (Previously Presented) The medical container of claim 63 wherein the spaces have a maximum reflectance of about twenty-five percent.

67. (Previously Presented) The medical container of claim 52 wherein the negative image bar code comprises a symbology selected from the group consisting of: Code 16K, Code 39, Code 49, Codabar, Code 128, UPC-E, UPC-A, EAN-8, EAN-13, Reduced Space Symbology, composite symbol, PDF-417, and Interleaved 2-of-5.

68. (Previously Presented) The medical container of claim 64 wherein the negative image bar code is a two-dimensional symbology.

69. (Previously Presented) The medical container of claim 64 wherein the negative image bar code has a length less than 72 millimeters and is characterized as having an A or B scan grade when decoded in accordance with

ANSIX3.182 through an overpouch having a thickness of at least 2 mils.

70. (Previously Presented) The medical container of claim 64 wherein the negative image bar code has a length less or equal to 52 millimeters and is characterized as having an A or B scan grade when decoded in accordance with ANSIX3.182 through an overpouch having a thickness of at least 2 mils.

71. (Previously Presented) The medical container of claim 6 wherein the first period of time is one day.

(9) EVIDENCE APPENDIX

None

(10) RELATED PROCEEDINGS APPENDIX

None